

CONTAINER ASSEMBLY FOR MIXING MATERIALS

RELATED APPLICATION

[0001] The subject patent application claims priority to all the benefits of U.S. Provisional Patent Application Serial No. 60/261,037, filed on January 10, 2001.

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0002] The subject invention relates to a container assembly for mixing materials and in particular for mixing liquid and dry reactants to form bone cement for use in surgical procedures.

2. Description of the Prior Art

[0003] It is well known that in many surgical procedures it is necessary to employ a cement or grouting type agent. The type of cement generally used for these procedures is formed of self-curing resins from the blending of a wide variety of liquid monomers or commoners with powdered polymers or copolymers, which forms a viscous mixture. When set, the resulting cements contain poly (methacrylic acid esters) as their main ingredient. The solid polymer powder is typically a finely divided air-fluffed powder which can also contain such things as radiopacifiers, antibiotics, plasticizers, crosslinking agents, and compositing reinforcing fibers or beads.

[0004] The mixture of the powder and liquid components develops a quick setting material and preparation of the cement usually occurs directly within the operating

room just prior to use. The mixing to form the cement typically occurs in a container assembly having a mixing device and a mixing chamber. These type of container assemblies are typically provided in two different forms.

[0005] One type of container assembly, which is disclosed in U.S. Patent No. 4,961,647, includes a mixing bowl having a mixing device. The powder is first placed in the mixing bowl, the liquid component is introduced, and then the mixing device is mounted to the container assembly. After the liquid and powder are mixed to form the cement, the cement can be scooped out of the container assembly with any suitable utensil.

[0006] Another type of container assembly, which is disclosed in U.S. Patent No. 5,265,956, includes a mixing bowl mounted to a cartridge. The mixing bowl also includes a mixing device. The powder is placed into the mixing bowl, the liquid component is introduced, and then the mixing device is mounted to the container assembly. After the liquid and powder are mixed to form the cement, the cement is transmitted into the cartridge. The cartridge is subsequently removed from the container assembly and mounted to an extrusion device.

[0007] The container assemblies of the prior art are effective in mixing and delivering the cement. However, there is little development in the prior art regarding the difficulties in introducing the powder to the mixing chamber while ensuring that the powder does not escape from the mixing chamber. As recognized by one skilled in the art, the finely divided air-fluffed powder used in these mixtures has a tendency to escape from the mixing chamber. The discharge of powder is undesirable because of the potential health hazard and the potential to contaminate the operating room. In

from the base. A lifting mechanism is disposed on at least one of the base and cover for automatically lifting the cover relative to the base as the cover is being removed from the base for preventing a discharge of material from the mixing chamber.

[0011] The subject invention therefore provide a container assembly which seals the mixing chamber with cover and subsequently controls the opening of the cover from the mixing chamber to reduce or eliminate the discharge of material.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] Other advantages of the present invention will be readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings wherein:

[0013] Figure 1 is a perspective view of a mixing device and a container assembly with the container assembly having a base and a storage cover;

[0014] Figure 2 is a cross sectional side view of the base with the cover mounted thereto;

[0015] Figure 3 is a cross sectional side view of the base with the cover being removed therefrom;

[0016] Figure 4A is an enlarged fragmented view of the base and the cover with the cover in a locked position;

[0017] Figure 4B is an enlarged fragmented view of the base and the cover with the cover in a partially released position;

[0018] Figure 4C is an enlarged fragmented view of the base and the cover with the cover in a fully released position;

[0019] Figure 5 is a top view of the base;

[0020] Figure 6 is a perspective view of the cover;

[0021] Figure 7 is a top view of the cover;

[0022] Figure 8 is a side view of the cover;

[0023] Figure 9 is an enlarged fragmentary view of the cover;

[0024] Figure 10 is a perspective view of an alternative embodiment of the cover;

[0025] Figure 11 is a side view of the alternative cover of Figure 10;

[0026] Figure 12 is a perspective view of a loading apparatus and an alternative container assembly with the container assembly having a base and a cover;

[0027] Figure 13 is a cross sectional side view of the loading apparatus and container assembly of Figure 12;

[0028] Figure 13A is an enlarged fragmentary view of the container assembly of Figure 12 further illustrating a piston;

[0029] Figure 14 is a perspective view of the container assembly of Figure 12;

[0030] Figure 14A is an enlarged fragmentary view of the base of Figure 14;

[0031] Figure 15 is a cross sectional side view of the base of Figure 12;

[0032] Figure 16 is a perspective view of the underside of the cover of Figure 12;

[0033] Figure 17 is a cross sectional side view of the cover of Figure 12;

[0034] Figure 18 is an enlarged fragmentary cross sectional view of the cover of Figure 12;

[0035] Figure 19A is an enlarged fragmentary view of the cover of Figure 12 in a locked position;

[0036] Figure 19B is an enlarged fragmentary view of the cover of Figure 12 in a released position;

[0037] Figure 20 is a perspective view of another alternative embodiment for the cover;

[0038] Figure 21 is a side view of the alternative cover of Figure 20.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0039] Referring to the Figures, wherein like numerals indicate like or corresponding parts throughout the several views, a container assembly for mixing materials is generally shown at 30 in Figure 1. As discussed in the background section, container assemblies of this type are typically used to mix a liquid monomer or comonomer (not shown) with powdered polymer or copolymer (not shown) to form a bone cement or grouting type agent used in certain surgical procedures. As also discussed above, the solid polymer powder is typically a finely divided air-fluffed powder. The container assembly 30 of the subject invention is pre-packed with the powder such that the container assembly 30 operates as both a storage container and a mixing container. It should be appreciated to those skilled in the art that although the forgoing disclosure only discusses the manufacture of bone cement, that the subject invention can be used to mix other materials without deviating from the scope of the appended claims.

[0040] Referring also to Figures 2 and 3, the container assembly 30 includes a base 32 having a top surface 34 and an inner wall 36. The inner wall 36 defines an upper surface 38 and a mixing chamber 40 for mixing the materials. The mixing chamber 40 is preferably a bowl shaped mixing chamber as is known in the art. Preferably, the top

surface 34 extends substantially transverse to the inner wall 36 and the base 32 further includes an outer ridge 42 extending upwardly from the top surface 34 substantially parallel with the upper surface 38 of the inner wall 36. The upper surface 38 of the inner wall 36 also includes a chamfer 44 angled inwardly toward the inner wall 36.

[0041] An outer wall 46 surrounds the inner wall 36 to define an evacuation chamber 48 therebetween. The top surface 34 includes at least one aperture 50 for evacuating gases from the mixing chamber 40 into the evacuation chamber 48. As best shown in Figure 1, the container assembly 30 also includes a bottom plate 52 and seal 54 mounted to an underside of the base 32 to enclose the evacuation chamber 48. A carbon filter 56 is mounted to the bottom plate 52. The carbon filter 56 is in fluid communication with an exhaust port 58 for removing gases from the evacuation chamber 48 during mixing of the liquid and powdered materials. A ventilation hole 60 is also provided within the outer wall 46. The evacuation chamber 48, filter 56, and exhaust port 58 of the base 32 are known features for this type of container assembly 30 and operate in a known manner. As such, these elements will not be discussed in any greater detail.

[0042] Referring also to Figures 4A through 5, a first locking device 62 is disposed on the top surface 34 of the base 32. In the embodiment of Figures 1 through 9, the first locking device 62 is defined as a first tab 62 extending substantially parallel to the top surface 34. The first tab 62 extends from the ridge 42 toward the inner wall 36.

[0043] A lifting mechanism 64 is also disposed on the base 32. As illustrated, the lifting mechanism 64 is defined as an angled step 64. Preferably there are three equally spaced first tabs 62 and three equally spaced angled steps 64. Even more preferably,

the first tabs 62 and angled steps 64 are spaced equally apart around the perimeter of the top surface 34. The purpose and operation of the first tabs 62 and angled steps 64 is discussed hereinbelow.

[0044] As shown in Figures 1 through 3, and in more detail in Figures 4A through 4C and 6 through 9, a cover 66 having an outer periphery 68 is provided and is selectively mounted to the base 32 covering the mixing chamber 40. A handle 70 is disposed on the cover 66 for allowing manipulation of the cover 66 relative to the base 32. In particular, the cover 66 seats upon the top surface 34 of the base 32 with the ridge 42 surrounding the outer periphery 68 of the cover 66 when the cover 66 is mounted to the base 32.

[0045] As best shown in Figure 1, a seal 72, preferably a rubber or foam gasket, is disposed between the cover 66 and the top surface 34 of the base 32 when the cover 66 is mounted to the base 32. The seal 72 assists in sealing the mixing chamber 40 and preventing the escape of material from the mixing chamber 40. The cover 66 may be removed from the base 32 exposing the mixing chamber 40. When the cover 66 is removed, a mixing device 74, also shown in Figure 1, is typically mounted to the base 32 to mix the materials. Mixing devices of this type are known in the art and as such will not be discussed in greater detail.

[0046] As best shown in Figures 2 through 4C, 6, 8, and 9, a sealing portion 76 depends from the cover 66 and engages the upper surface 38 of the inner wall 36 when the cover 66 is mounted to the base 32. The sealing portion 76 is at least partially flexible and angled outwardly toward the outer periphery 68 such that during the engagement of the sealing portion 76 with the upper surface 38, the sealing portion 76

flexes and conforms to the upper surface 38 to seal the mixing chamber 40. The flexing of the sealing portion 76 compensates for any manufacturing defects or tolerances in both the cover 66 and the base 32. Hence, an adequate seal is provided between the cover 66 and the base 32.

[0047] Preferably, the sealing portion 76 is spaced inwardly from the outer periphery 68. In addition, the sealing portion 76 is preferably angled outwardly toward the outer periphery 68 from 0.5 to 20 degrees. More preferably, the sealing portion 76 is angled outwardly toward the outer periphery 68 from 2 to 10 degrees, and most preferably, the sealing portion 76 is angled outwardly toward the outer periphery 68 approximately 6.4 degrees. As appreciated, the particular angle of the sealing portion 76 can vary so long as an adequate seal between the cover 66 and the base 32 is maintained. As illustrated, the sealing portion 76 is defined as an annular wedge 76 having a first end and a distal second end. The first end is mounted to the cover 66 and is thicker than the distal end when viewed in cross section, see Figure 9, to at least partially provide the flexibility of the sealing portion 76. The distal second end also includes a beveled section 78 to further provide the flexibility of the sealing portion 76. The thicker first end of the annular wedge 76 provides a spring loading function for the sealing portion 76 to encourage biased deformation of the thinner distal second end.

[0048] In the preferred embodiment, the sealing portion 76 is integrally formed with the cover 66. Even more preferably, the cover 66 and sealing portion 76 are integrally formed of a polymeric material. It should be appreciated that the cover 66 and sealing portion 76 may be formed of any suitable material.

[0049] In the embodiment of Figures 1 through 9, a second locking device 80 is disposed on the outer periphery 68 of the cover 66 wherein the first 62 and second 80 locking devices interlock the cover 66 to the base 32 when the cover 66 is mounted to the base 32 and release the cover 66 from the base 32 as the cover 66 is being removed from the base 32. As best shown in Figures 4A through 4C and 6 through 8, the second locking device 80 is defined as a second tab 80 extending from the outer periphery 68 of the cover 66 and frictionally engaging the first tab 62 when the cover 66 is interlocked to the base 32. The second tab 80 of the cover 66 includes a tapered portion 82 which assists in the mounting and removal of the cover 66 to the base 32. The second tab 80 also engages the lifting mechanism 64, or angled step 64, of the base 32 when the cover 66 is being removed from the base 32, see Figure 4C. The engagement of the second tab 80 with the angled step 64 provides a controlled lifting feature of the cover 66 relative to the base 32 during removal of the cover 66 from the base 32.

[0050] A stop mechanism 84 is disposed on the cover 66 to limit a rotatable movement of the cover 66 relative to the base 32. In the embodiment of Figures 1 through 9, the stop mechanism 84 is defined as a stop tab 84 extending from the cover 66 whereby the stop tab 84 selectively engages the first tab 62 of the base 32 during a rotation of the cover 66 relative to the base 32.

[0051] The operation of the container assembly 30 of Figures 1-9 is now discussed in greater detail. During installation of the cover 66 to the base 32, the annular wedge 76 of the cover 66 engages the chamfer 44 on the upper surface 38 of the inner wall 36 and flexes or otherwise deforms to conform to the configuration of the upper surface

38. Hence, the chamfer 44 guides the distal second end of the annular wedge 76 into the mixing chamber 40 as the cover 66 is mounted to the base 32. The flexing of the annular wedge 76 continues until the second tab 80 and stop tab 84 engage the top surface 34 of the base 32. A portion of the outer periphery 68 of the cover 66 also engages the top surface 34. In addition, the seal 72, if used, is wedged between the outer periphery 68 of the cover 66 and the top surface 34 of the base 32. In this position, the annular wedge 76 of the cover 66 is biased and sealed against the chamfer 44 of the base 32. The cover 66 is then rotated clockwise relative to the base 32 which positions the tapered portions 82 of the second tabs 80 under the first tabs 62 of the base 32. The second tabs 80 then engage the first tabs 62 which completely close the cover 66 onto the base 32. The clockwise rotation continues until the stop tab 84 engages one of the angled steps 64, see Figure 4A. The cover 66 is now interlocked and sealed to the base 32 which prevents the powder from escaping from the mixing chamber 40.

[0052] During removal of the cover 66, the cover 66 is initially interlocked with the base 32 as shown in Figure 4A. A user then grasps the handle 70 and rotates the cover 66 counter-clockwise. The second tabs 80 will disengage from under the first tabs 62 and the stop tab 84 will rotate away from the adjacent angled step 64, see Figure 4B. The second tabs 80 will then engage the angled steps 64 which automatically lifts the cover 66 relative to the base 32 as the cover 66 is being removed. This controlled lifting of the cover 66 prevents the discharge of material from the mixing chamber 40 by controlling the flexure of the annular wedge 76 against the inner wall 36. The counter-clockwise rotation and lifting of the cover 66 continues until the second tab 80

has reached the top of the associated angled step 64, see Figure 4C. In this position the annular wedge 76 has returned to the position adjacent the chamfer 44 of the inner wall 36. The annular wedge 76 has little resistance with the inner wall 36 such that the cover 66 can be easily removed from the base 32.

[0053] Referring to Figures 10 and 11, an alternative embodiment of the cover 66 is shown. The cover 66 shown in these Figures includes a sealing portion 76 in accordance with the subject invention spaced inwardly from an outer periphery 68. The cover 66 does not include a locking device or a stop mechanism.

[0054] Turning to Figures 12 through 19B, an alternative embodiment of the subject invention is shown wherein like numerals increased by one hundred indicate like or corresponding parts throughout the several views. Referring to Figures 12 and 13, a container assembly for mixing materials is generally shown at 130 and a loading apparatus is generally shown at 190. As with the primary embodiment outlined above, the container assembly 130 of the subject invention is pre-packed with the powder such that the container assembly 130 operates as both a storage container and a mixing container.

[0055] The loading apparatus 190 includes a cartridge 192 located below the container assembly 130 for receiving mixed bone cement therefrom. The cartridge 192 and the cartridge 192 is mounted to a vacuum shroud 196. Once filled, the cartridge 192 can be removed from both the vacuum shroud 196 and container assembly 130, and be subsequently mounted to an extrusion device (not shown). Loading apparatuses of this type are well known in the art and will not be discussed in any greater detail.

[0056] Referring also to Figures 14 and 15, the container assembly 130 includes a base 132 having a top surface 134 and an inner wall 136. The inner wall 136 defines an upper surface 138 and a mixing chamber 140 for mixing the materials. The mixing chamber 140 has a frusto-conical funnel-type shape terminating at a bottom opening 141. The upper surface 138 of the inner wall 136 includes a chamfer 144 angled inwardly toward the inner wall 136.

[0057] The top surface 134 extends substantially transverse to the inner wall 136 with a first locking device 162 being disposed on the top surface 134 of the base 132. In the embodiment of Figures 12 through 19B, the first locking device 162 is defined as a first tab 162 extending outwardly from the top surface 134 wherein the first tab 162 of the base 132 includes a tapered portion 182. The tapered portion 182 is best shown in Figure 14A. Preferably there are three equally spaced first tabs 162 disposed about the top surface 134 of the base 132 with a notch 186 being formed between each of the first tabs 162. The purpose and operation of the first tabs 162 is discussed hereinbelow. The top surface 134 also includes an aperture 150 for evacuating gases from the mixing chamber 140.

[0058] Referring to Figures 13, 13A, and 14, a piston 194 is disposed between the bottom opening 141 of the base 132 and the cartridge 192. The bottom opening 141 includes an annular rib 143 and the piston 194 includes an annular notch 195 for engaging the rib 143 to retain the piston 194 in position. The piston 194 also includes an annular sealing ring 197 which engages the bottom opening 141 to seal the bottom opening 141 and prevent the escape of powder from the mixing chamber 140. The sealing ring 197 is at least partially flexible and angled outwardly toward the bottom

opening 141 such that the sealing ring 197 flexes and conforms to the bottom opening 141 to seal the bottom opening 141.

[0059] As shown in Figures 12 through 14, and in more detail in Figures 16 through 19B, a cover 166 having an outer periphery 168 is provided and is selectively mounted to the base 132 covering the mixing chamber 140. A handle 170 is disposed on the cover 166 for allowing manipulation of the cover 166 relative to the base 132.

[0060] The cover 166 further includes an outer flange 188 substantially encapsulating the top surface 134 of the base 132 when the cover 166 is mounted to the base 132. In particular, the cover 166 seats upon the top surface 134 of the base 132 with the flange 188 surrounding the top surface 134 and first tabs 162. A seal 172, preferably a rubber or foam gasket, is disposed between the cover 166 and the top surface 134 of the base 132 when the cover 166 is mounted to the base 132, see Figure 14. The seal 172 assists in sealing the mixing chamber 140 and preventing the escape of material from the mixing chamber 140.

[0061] A sealing portion 176 depends from the cover 166 and engages the upper surface 138 of the inner wall 136 when the cover 166 is mounted to the base 132. The sealing portion 176 is at least partially flexible and angled outwardly toward the outer periphery 168 such that during the engagement of the sealing portion 176 with the upper surface 138, the sealing portion 176 flexes and conforms to the upper surface 138 to seal the mixing chamber 140.

[0062] Preferably, the sealing portion 176 is spaced inwardly from the flange 188. In addition, the sealing portion 176 is preferably angled outwardly toward the outer periphery 168 from 0.5 to 20 degrees. More preferably, the sealing portion 176 is

angled outwardly toward the outer periphery 168 from 2 to 10 degrees, and most preferably, the sealing portion 176 is angled outwardly toward the outer periphery 168 at approximately 7.5 degrees. As discussed above with regard to the primary embodiment, the particular angle of the sealing portion 176 can vary so long as an adequate seal between the cover 166 and the base 132 is maintained. The sealing portion 176 is defined as an annular wedge 176 having a first end and a distal second end. The first end is mounted to the cover 166 and is thicker than the distal end when viewed in cross section to at least partially provide the flexibility of the sealing portion 176. The thicker first end of the annular wedge 76 provides a spring loading function for the sealing portion 76 to encourage biased deformation of the thinner distal second end.

[0063] In the preferred embodiment, the sealing portion 176 is integrally formed with the cover 166. Even more preferably, the cover 166 and sealing portion 176 are integrally formed of a polymeric material.

[0064] In the embodiment of Figures 12 through 19B, a second locking device 180 is disposed on the cover 166 wherein the first 162 and second 180 locking devices interlock the cover 166 to the base 132 when the cover 166 is mounted to the base 132 and release the cover 166 from the base 132 as the cover 166 is being removed from the base 132. As best shown in Figures 16 through 19B, the second locking device 180 is defined as a second tab 180 being supported by the flange 188 and frictionally engaging the first tab 162 when the cover 166 is interlocked to the base 132. The second tab 180 of the cover 166 includes a raised portion 198 which engages the first tab 162 of the base 132 to assists in the mounting and removal of the cover 166 to the

base 132. As best shown in Figures 17 and 18, the second tab 180 is spaced from a main body portion 167 of the cover 166 to create a gap between the second tab 180 and the cover 166. The first tab 162 becomes wedged between the main body portion 167 of the cover 166 and the second tab 180 within the gap when the cover 166 is mounted to the base 132.

[0065] The cover 166 further includes a lifting mechanism 164 disposed adjacent the flange 188 for automatically lifting the cover 166 relative to the base 132 during a removal of the cover 166. In the embodiment of Figures 12 through 19B, the lifting mechanism 164 is defined as an angled step 164 mounted to the cover 166 engaging the first tab 162 of the base 132. Preferably, there are three second tabs 180 and three angled steps 164 on the cover 166. The engagement of the first tab 162 with the angled step 164 provides a controlled lifting feature of the cover 166 relative to the base 132 during removal of the cover 166 from the base 132.

[0066] A stop mechanism 184 is disposed on the cover 166 to limit a rotatable movement of the cover 166 relative to the base 132. In the embodiment of Figures 12 through 19B, the stop mechanism 184 is defined as an appendage 184 extending from the lifting mechanism 164 on the cover 166 whereby the appendage 184 selectively engages the first tab 162 of the base 132 during a rotation of the cover 166 relative to the base 132.

[0067] The operation of the container assembly 130 of Figures 12 through 19B is now discussed in greater detail. During installation of the cover 166 to the base 132, the annular wedge 176 of the cover 166 engages the chamfer 144 on the upper surface 138 of the inner wall 136 and flexes or otherwise deforms to conform to the configuration

of the upper surface 138. Hence, the chamfer 144 guides the distal second end of the annular wedge 176 into the mixing chamber 140 as the cover 166 is mounted to the base 132. The flexing of the annular wedge 176 continues until the cover 166 engages the top surface 134 of the base 132. The flange 188 encompasses the first tabs 162 and top portion of the base 132 and the second tabs 180 are seated within the notches 186 of the base 132. In addition, the seal 172, if used, is wedged between the cover 166 and the top surface 134 of the base 132. In this position, the annular wedge 176 of the cover 166 is biased and sealed against the chamfer 144 of the base 132.

[0068] The cover 166 is then rotated clockwise relative to the base 132 which moves the second tabs 180 within the notches 186 until second tabs 180 engage the tapered portions 182 of the first tabs 162. The second tabs 180 then move into wedging engagement with the first tabs 162 which further close the cover 166 onto the base 132. In particular, the raised portion 198 of the second tabs 180 engages the first tabs 162. The clockwise rotation continues until the stop tabs 184 engage one of the first tabs 162 as shown in Figure 19A. The cover 166 is now interlocked and sealed to the base 132 which prevents the powder from escaping from the mixing chamber 140.

[0069] During removal of the cover 166, a user grasps the handle 170 and rotates the cover 166 counter-clockwise. The second tabs 180 will disengage from the first tabs 162 and the stop tabs 184 will rotate away from the adjacent first tabs 162. In particular, the second tabs 180 will re-align with the notches 186 of the base 132. The angled steps 164 of the cover 166 will then engage the first tabs 162 of the base 132 which automatically lifts the cover 166 relative to the base 132 as the cover 166 is being removed. This controlled lifting of the cover 166 prevents the discharge of

material from the mixing chamber 140 by controlling the flexure of the annular wedge 176 against the inner wall 136. The counter-clockwise rotation and lifting of the cover 166 continues until the stop tab 184 again engages the first tabs 162 of the base 132 as shown in Figure 19B. In this position the annular wedge 176 has returned to the position adjacent the chamfer 144 of the inner wall 136. The annular wedge 176 has little resistance with the inner wall 136 such that the cover 166 can be easily removed from the base 132.

[0070] Turning to Figures 20 and 21, yet another alternative embodiment of the cover 166 is shown. This embodiment of the cover 166 does not include an outer flange or a locking device. A sealing portion 176 in accordance with the subject invention extends from the cover 166 and is spaced inwardly from an outer periphery 168.

[0071] Obviously, many modifications and variations of the present invention are possible in light of the above teachings such that the invention may be practiced otherwise than as specifically described within the scope of the appended claims.